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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/872,769	05/31/2001	Dennis M. Brown	A-70600/RFT/AMS	1226

7590 02/11/2003

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EXAMINER
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DEWITTY, ROBERT M

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 02/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

09/872,769

Applicant(s)

BROWN, DENNIS M.

Examiner

Robert M DeWitty

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 November 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 4-10 and 14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 4-10, and 14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Claims 1, 4-10, and 14 are pending in the instant application. Acknowledgement is made of Applicant's amendments and arguments submitted 11/25/02.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1, 4-10, and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Independent claim 1 contains the limitation "each in an amount sufficient to modulate said cellular proliferative disease". This limitation is indefinite because the instant specification teaches that any suitable dosage may be administered in the methods of the invention. One with ordinary skill in the art would not know what amount would bring about sufficient modulation of the proliferative disease. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1, 4-10, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Francis (U.S. Pat. No. 4,797,388), further in view of Levin et al. ("Chemotherapeutic approaches to brain tumors").

Francis relates to improved pharmaceutical compositions containing galactitol as a carrier for a therapeutic agent. Therapeutic agents include cytotoxic agents such as vincristine, doxorubicin, daunorubicin, and cisplatin. Galactitol compound is taught to enhance the chemical and physical stability of the drug.

Levin teaches the combination of dianhydrogalactitol and BCNU. Levin teaches that the results of the BCNU-DAG studies show that antitumor activity of the hexitol epoxides may be enhanced by drug combination studies. In the Materials and Methods section, Levin teaches the preparation of dianhydrogalactitol injection formulations and BCNU injection formulations (page 126). It is disclosed that dianhydrogalactitol is active before BCNU therapy, thus indicating that dianhydrogalactitol is administered before BCNU (page 130)

One with ordinary skill in the art would have been motivated to utilize dianhydrogalactitol (a galactitol compound) with cytotoxic agents such as vincristine, doxorubicin, daunorubicin or cisplatin because the art (Levin) teaches that hexitol epoxides antitumor activity can be enhanced through drug combinations. As vincristine, doxorubicin, danuorubicin, and cisplatin well-known antitumor agents, one with ordinary skill would believe they would be suitable for combination with dianhydrogalactitol to enhance its' activity.

### ***Response to Arguments***

3. In view of Applicant's response to the rejection of claim 14 under 35 USC 132, the rejection is withdrawn.

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4. In view of Applicant's amendment to claim 1, namely addition of the limitation of dianhydrogalactitol, the rejection over Barnett under 35 USC 103 is withdrawn.

5. Applicant's arguments have been fully considered but they are not persuasive. Applicant argues that Francis does not teach the use of dianhydrogalactitol, and Levin does not teach an antiproliferative agent as in claim 1. The examiner reminds the Applicant that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, whereas Francis does not teach dianhydrogalactitol however, as galactitol is an analog thereof, Levin clearly teaches the use of such galactitol. Further, whereas Levin does not teach an antiproliferative agent as in claim 1, Francis teaches using such agents in a pharmaceutical composition. As stated above, one with ordinary skill in the art would have been motivated to utilize the antiproliferative agents of Francis with dianhydrogalactitol because of the suggestion by Levin that the activity of a galactitol can be enhanced through drug combination therapy. The use of antiproliferative agents as taught by Francis would have been obvious because of their known cytotoxic activity. Thus the rejection is maintained.

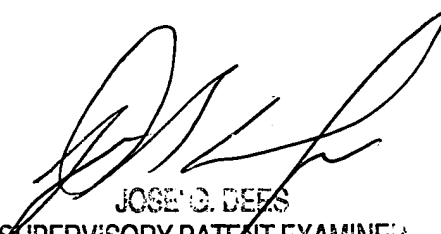
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M DeWitty whose telephone number is 703-308-2411. The examiner can normally be reached on 9:00am - 5:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4527. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7924 for regular communications and 703-308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

RMD  
February 6, 2003



JOSE C. DEES  
SUPERVISORY PATENT EXAMINER

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